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APPLICATION NO.	NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/001,844	11/16/2001		C. Frank Bennett	ISPH-0617	2097	
26259	7590	09/27/2004		EXAMINER		
LICATLA &		ELL P.C.	SCHULTZ, JAMES			
66 E. MAIN MARLTON,		53		ART UNIT PAPER NUMBER		
,	,			1635		
				DATE MAILED: 09/27/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/001,844	BENNETT ET AL.					
Office Action Summary	Examiner	Art Unit					
	J. D. Schultz, Ph.D.	1635					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM							
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time y within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE!	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 14 S	September 2004.						
·— ·	·						
•	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) Claim(s) 1.5-10 and 12-15 is/are pending in the 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed.  6) Claim(s) 1.5-10 and 12-15 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/of the specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correction.	er.  cepted or b) objected to by the drawing(s) be held in abeyance. Section is required if the drawing(s) is objected.	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)							
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li> </ol>	4) Interview Summary Paper No(s)/Mail D  5) Notice of Informal F 6) Other:						

Application/Control Number: 10/001,844

Art Unit: 1635

### **DETAILED ACTION**

## Status of Application/Amendment/Claims

Applicant's response after final filed September 14, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed June 24, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments with respect to claims 1, 5-10, and 12-15 have been considered but are most in view of the new ground(s) of rejection set forth below.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, and by dependency claims 5-10 and 12-15, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Applicants amended claims 1, 5-10 and 12-15 are drawn to compounds 8 to 50

Application/Control Number: 10/001,844

Art Unit: 1635

nucleotides in length targeted to nucleobases 501 through 926 of a nucleotide encoding Sonic Hedgehog (SHH) of SEQ ID NO: 3.

A thorough review of the specification and particularly of Table 1, which lists the oligos targeting SEQ ID NO: 3, indicates that applicants had not, previous to this amendment, disclosed targeting the entirety of the newly recited target region of 501 through 926 of a nucleotide encoding Sonic Hedgehog (SHH) of SEQ ID NO: 3. Accordingly, the instant specification is not considered to support claims directed to the region of 501 through 926, and is thus considered to introduce new matter. For example, applicants teach targeting using 20mer oligos nucleotides 721 through 741, and to 790 through 810 of the instant SEQ ID NO: 3, but do not teach targeting nucleotides 742-789 as now claimed. If applicant disagrees, applicant is requested to indicate with particularity by page and line number where such support exists for the targeting of the entirety of the region now claimed.

### Prior Art

Rejections under 35 U.S.C. § 112 first paragraph notwithstanding, claims 1, 5-10 and 12-15 are considered to be free of the prior art searched.

#### Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

**JDS** 

JD Schultz

Patent Examiner,

Art Unit 1635